

the claims, is attached herewith as Appendix A. For the Examiner's convenience, a complete claim set of the currently pending claims is also submitted herewith as Appendix B.

REMARKS

Status of the Claims.

Claims 2-13, 17,23, and 51-64 are pending with entry of this amendment. Claims 1, 14-16 and 65-67 were previously canceled without prejudice to subsequent renewal. Claims 2, 18, 22, 23, 51, 52, 53, 56, and 64 are amended herein. These amendments introduce no new matter and are fully supported throughout the specification. For example, specific support for some of the amendments is provided in the specification, including at, e.g., page 54, line 10 to page 55, line 30; and page 39, line 9 to page 43, line 16. Claims 22 and 23, which are dependent upon claim 18, have been amended for consistency and proper antecedent basis. Claims 52, 53, 56, and 64, dependent upon claim 51, have been amended for consistency and proper antecedent basis.

Information Disclosure Statement.

Applicants thank the Examiner for indicating that he did not receive copies of references cited as Items 1-81 on the IDS mailed to the USPTO on March 25, 2002. On October 22, 2002 Applicants re-submitted copies of Reference Items 1-81 of that IDS, as well as copies of the IDS, PTO Form 1449, transmittal form, and Communication previously filed with the USPTO on March 25, 2002. Also included in that submission were copies of two return postcards that were mailed with these documents and copies of all references cited on the IDS on March 25, 2002. Both return postcards were date-stamped by the USPTO mailroom on March 29, 2002, indicating receipt of all documents, including the reference copies (which were divided amongst two boxes mailed to the USPTO). Applicants respectfully request that references corresponding to Items 1-81 on the IDS be considered by the Examiner in this application and that the Examiner provide an initialed copy of the Form PTO. Applicants thank the Examiner for his consideration of the references cited as Items 82-428 on the IDS submitted on March 25, 2002.

Non-Statutory Obviousness-Type Double Patenting.

Claims 2-13 and 17 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 38-49 of copending USSN 09/021,769. Claims 18-21 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 51-54 of copending USSN 09/021,769. Claims 51-54 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 51-54 of copending USSN 09/021,769.

This rejection has been mooted because commonly assigned USSN 09/021,769 has been abandoned. Accordingly, Applicants respectfully request withdrawal of the rejection.

35 U.S.C. §112, Second Paragraph.

Claims 18-23, 51-58, and 64 were rejected under 35 U.S.C. §112, second paragraph, as allegedly incomplete for omitting specific steps. The Examiner found that the specific omitted steps were "how to determine whether the recombinant cell-specific binding moiety polypeptide has enhanced ability to bind to the target cell, what is the control that is compared to determine enhanced ability to bind the target cell." Office Action, p. 6. This rejection has been overcome by the amendments to the claims.

Independent claim 18 has been amended to recite more specifically a method for obtaining a recombinant cell-specific binding moiety for an ability to increase uptake, efficacy, or specificity of a vaccine or antigen for a target cell, the method comprising: (1) recombining at least first and second forms of at least one nucleic acid, wherein each of the first and second forms of the nucleic acid comprises a polynucleotide which encodes a binding moiety polypeptide of an enterotoxin, wherein the first and second forms differ from each other in two or more nucleotides, to produce a library of recombinant nucleic acids; (2) producing a library of vectors from the library of recombinant nucleic acids, wherein each vector comprises a member of the library of recombinant nucleic acids; (3) introducing one or more members of the library of vectors into one or more host cells, wherein the one or more members of the library of recombinant nucleic acids are expressed to form one or more recombinant cell-specific binding moiety polypeptides and recovering the one or

more recombinant cell-specific binding moiety polypeptides; (4) contacting the one or more recombinant cell-specific binding moiety polypeptides with a cell surface receptor of a target cell; and (5) *determining which of the one or more recombinant cell-specific binding moiety polypeptides exhibits an enhanced ability to bind to the target cell compared to the ability of a binding moiety polypeptide encoded of (1) to bind to the target cell.*

Independent claim 51 has been similarly amended to recite more particularly a method for obtaining a recombinant cell-specific binding moiety polypeptide for an ability to increase uptake, efficacy, or specificity of a vaccine antigen for a target cell, the method comprising: (1) recombining at least first and second forms of at least one nucleic acid that comprises a polynucleotide which encodes a cell-specific binding moiety polypeptide, wherein the first and second forms differ from each other in two or more nucleotides, to produce a library of recombinant nucleic acids; (2) introducing one or more members of a library of vectors, each of which comprises a member of the library of recombinant nucleic acids, into one or more host cells, wherein one or more members of the library of recombinant nucleic acids are expressed to form one or more recombinant cell-specific binding moiety polypeptides; (3) contacting the one or more recombinant cell-specific binding moiety polypeptides with a cell surface receptor of a target cell; (4) *determining which of the one or more recombinant cell-specific binding moiety polypeptides exhibits an enhanced ability to bind to the target cell compared to the ability of the cell-specific binding moiety polypeptide of (1) to bind the target cell;* and (5) fusing or linking the recombinant cell-specific binding moiety polypeptide to the vaccine antigen or coating the vaccine antigen with the recombinant cell-specific binding moiety polypeptide. Through this method, recombinant polypeptide(s) that have a greater ability to bind a target cell compared to the ability of a polypeptide encoded by a non-recombinant polynucleotide of (1) are identified. Thus, by these amendments, Applicants believe the rejection of claims 18 and 51, and all claims dependent thereon, is overcome and respectfully request that the rejection be withdrawn.

35 U.S.C. §103(a).

Claims 51-58 and 64 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Stemmer et al., WO 97/20078 (1997) in view of Ledley et al. WO 94/25608 (1994), and Patten

at al., *Current Opinion in Biotechnology* 8:724-733 (1997). Office Action, p. 7. According to the Examiner, however, it "would have been obvious for one of ordinary skill in the art at the time of the invention to substitute the first and second forms of polypeptide sequences taught by Stemmer with polynucleotide sequences encoding a DNA-binding element and a ligand binding . . . [element] as taught by Ledley for the production of a genetic vaccine as taught by Patten." *Id.* at p. 9.

Applicants respectfully traverse the rejection and submit that the Examiner has not established a *prima facie* case of obviousness for any of claims 51-58 or 64. To establish a *prima facie* case of obviousness, the Office must demonstrate that: (1) the cited reference or references teach or suggest every element of the claimed invention; (2) there is some suggestion in a particular cited reference or combination of cited references to modify the cited reference or to combine the teachings of the cited references to arrive at the claimed invention; and (3) there is a reasonable expectation of success in carrying out or arriving at the claimed invention based on the teachings of the cited references.

First, Applicants respectfully submit the Examiner has failed to establish sufficiently and specifically where each of the cited references discloses each of the limitations of claims 51-58 and 64. Second, the Examiner has failed to demonstrate sufficiently that there is any specific suggestion in the cited references to combine their teachings to arrive at the claimed invention as defined by independent claim 51 and claims 52-58 and 64 dependent thereon. Third, Applicants respectfully submit that the Examiner has not sufficiently shown that there would be any reasonable expectation of success in carrying out or arriving at the claimed invention, as explicitly defined by claim 51 (or claims 52-58 and 64 dependent thereon) based on the teachings of the cited references.

In the interest of brevity, the following remarks focus on the Ledley and Patten references because the Examiner relied on this reference as teaching the application of the Stemmer methods for the production of a vaccines. The Examiner will, of course, appreciate that Applicants' remarks relate to the cited combination of references over which the claims were rejected. Simply dismissing Applicants' arguments as directed to the references individually would therefore be inappropriate.

As amended, independent claim 51 recites:

A method for obtaining a recombinant cell-specific binding moiety polypeptide for an ability to increase uptake, efficacy, or specificity of a vaccine antigen for a target cell, the method comprising: (1) recombining at least first and second forms of at least one nucleic acid that comprises a polynucleotide which encodes a cell-specific binding moiety polypeptide, wherein the first and second forms differ from each other in two or more nucleotides, to produce a library of recombinant nucleic acids; (2) introducing one or more members of a library of vectors, each of which comprises a member of the library of recombinant nucleic acids, into one or more host cells, wherein one or more members of the library of recombinant nucleic acids are expressed to form one or more recombinant cell-specific binding moiety polypeptides; (3) contacting the one or more recombinant cell-specific binding moiety polypeptides with a cell surface receptor of a target cell; (4) determining which of the one or more recombinant cell-specific binding moiety polypeptides exhibits an enhanced ability to bind to the target cell compared to the ability of the cell-specific binding moiety polypeptide of (1) to bind the target cell; and (5) fusing or linking the recombinant cell-specific binding moiety polypeptide to the vaccine antigen or coating the vaccine antigen with the recombinant cell-specific binding moiety polypeptide.

Independent claim 51 recites that *the cell-specific binding moiety polypeptide is fused or linked to or coated on the antigen*. See Claim 51(5). Claim 58 recites a composition in which an *enhanced cell-specific binding polypeptide is fused or linked to, or coated on, a heterologous polypeptide antigen*.

Ledley teaches a chimeric protein that comprises a ligand binding element, but this element is linked to a DNA-binding element, not a polypeptide antigen. Ledley's chimeric protein is intended for use in targeting DNA vectors for use in gene therapy. Ledley teaches that protein/DNA complexes useful in gene therapy should not be antigenic. See Ledley, page 2, line 35 – page 3, line 2. Thus, Ledley teaches away from a cell-specific binding polypeptide is fused or linked to, or coated on, a heterologous polypeptide *antigen*. In addition, as discussed above, Ledley neither teaches nor suggests a ligand binding element that exhibits *an enhanced ability to bind to a target cell*.

Ledley also fails to teach or suggest any modification of the ligand binding element for any purpose. *See, e.g.*, Ledley, page 7, lines 12-19; page 14, lines 12-15; page 14, line 35 – page 15, line 1; page 15, lines 19-21.

Claim 58, which is dependent upon claim 51, recites:

A composition for eliciting an immune response comprising an antigen and a recombinant cell-specific binding moiety polypeptide, wherein the composition is produced by the method of claim 51, wherein:

- (i) the antigen comprises a polypeptide antigen;
- (ii) the cell-specific binding moiety polypeptide exhibits enhanced ability to bind to the target cell; and
- (iii) the polypeptide antigen and the recombinant cell-specific binding moiety polypeptide are derived from different polypeptides.

The Examiner has identified no compositions that combine an enhanced cell-specific binding moiety polypeptide with a heterologous protein antigen in any of the references of record.

Nothing in Patten remedies the deficiencies of Ledley or the fact that Ledley teaches away from the claimed invention as explicitly defined by claim 51 and claims 52-58 and 64 dependent thereon.

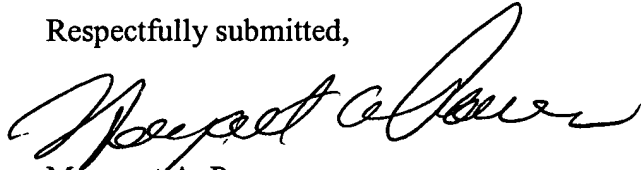
For at least these reasons and those discussed above, Applicants respectfully submit that no *prima facie* case of obviousness has been established. Applicants submit that the rejection cannot be maintained and respectfully request that the rejection of independent claim 51, and claims 52-58 and 64 dependent thereon, be withdrawn.

CONCLUSION

In view of the foregoing, Applicants believes all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (650) 298-5809.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Margaret A. Powers', written in a cursive style.

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APPENDIX A

**"MARKED UP" CLAIMS ILLUSTRATING THE AMENDMENTS MADE TO THE
CLAIMS OF 09/247,886 WITH ENTRY OF THIS AMENDMENT**

2. (Amended Three Times) A method for obtaining **[producing and screening]** a recombinant cell-specific binding moiety for an ability to increase uptake or specificity of a genetic vaccine for a target cell, the method comprising:

(1) recombining at least first and second forms of at least one nucleic acid, wherein each of the first and second forms of the nucleic acid comprises a polynucleotide that encodes a nucleic acid binding domain and at least first and second forms of at least one additional nucleic acid, wherein each of the first and second forms of the additional nucleic acid comprises a polynucleotide that encodes a cell-specific ligand that specifically binds to a protein on the surface of a cell of interest, wherein the first and second forms of each nucleic acid differ from each other in two or more nucleotides, to produce a library of recombinant binding moiety-encoding nucleic acids;

(2) producing a library of vectors from the library of recombinant binding moiety-encoding nucleic acids, wherein each vector comprises: a) a binding site specific for the nucleic acid binding domain and b) a member of the library of recombinant binding moiety-encoding nucleic acids;

(3) introducing one or more members of the library of vectors into one or more host cells, wherein the encoded recombinant binding moiety is expressed and recovering the expressed recombinant binding moiety;

(4) binding the expressed recombinant binding moiety to a vector comprising the binding site to form a vector-binding moiety complex;

(5) contacting the vector-binding moiety complex with a target cell of interest;
and

(6) determining if one or more target cells contain a vector from the vector-binding moiety complex, and recovering the recombinant cell-specific binding moiety nucleic acid from any such target cells.

18. (Amended Four Times) A method for obtaining [producing and screening] a recombinant cell-specific binding moiety for an ability to increase uptake, efficacy, or specificity of a vaccine or antigen for a target cell, the method comprising:

(1) recombining at least first and second forms of at least one nucleic acid, wherein each of the first and second forms of the nucleic acid comprises a polynucleotide which encodes a binding moiety polypeptide of an enterotoxin, wherein the first and second forms differ from each other in two or more nucleotides, to produce a library of recombinant nucleic acids;

(2) producing a library of vectors from the library of recombinant nucleic acids, wherein each vector comprises a member of the library of recombinant nucleic acids;

(3) introducing one or more members of the library of vectors into one or more host cells, wherein the one or more members of the library of recombinant nucleic acids are [is] expressed to form one or more [a] recombinant cell-specific binding moiety polypeptides and recovering the one or more recombinant cell-specific binding moiety polypeptides;

(4) contacting the one or more recombinant cell-specific binding moiety polypeptides with a cell surface receptor of a target cell; and

(5) determining [if the] which of the one or more recombinant cell-specific binding moiety polypeptides exhibits an enhanced ability to bind to the target cell compared to the ability of a binding moiety polypeptide encoded of (1) to bind to the target cell.

22. (Amended Twice) A method for producing a composition for eliciting an immune response, the method comprising coating a polynucleotide that is capable of expressing an antigen with a recombinant cell-specific binding moiety polypeptide produced by the method of claim 18.

23. (Amended Twice) The method of claim 18, wherein each of the one or more recombinant cell-specific binding moiety polypeptides is expressed as a fusion protein on the surface of a replicable genetic package.

51. (Amended Twice) A method for obtaining [producing and screening] a recombinant cell-specific binding moiety polypeptide for an ability to increase uptake, efficacy, or specificity of a vaccine antigen for a target cell, the method comprising:

(1) recombining at least first and second forms of at least one nucleic acid that comprises a polynucleotide which encodes a cell-specific binding moiety polypeptide, wherein the first and second forms differ from each other in two or more nucleotides, to produce a library of recombinant nucleic acids;

(2) introducing one or more members of a library of vectors, each of which comprises a member of the library of recombinant nucleic acids, into one or more host cells, wherein [the] one or more members of the library of recombinant nucleic acids are [is] expressed to form one or more [a] recombinant cell-specific binding moiety polypeptides;

(3) contacting the one or more recombinant cell-specific binding moiety polypeptides with a cell surface receptor of a target cell;

(4) determining [if the] which of the one or more recombinant cell-specific binding moiety polypeptides exhibits an enhanced ability to bind to the target cell compared to the ability of the cell-specific binding moiety polypeptide of (1) to bind the target cell; and

(5) fusing or linking the recombinant cell-specific binding moiety polypeptide to the vaccine antigen or coating the vaccine antigen with the recombinant cell-specific binding moiety polypeptide.

52. (Amended) The method of claim 51, wherein each of the one or more recombinant cell-specific binding moiety polypeptides is expressed as a fusion protein on the surface of a replicable genetic package.

53. (Amended Twice) The method of claim 51, wherein each of the one or more recombinant cell-specific binding moiety polypeptides is fused or linked to the vaccine antigen.

56. (Amended Twice) The method of claim 51, wherein each of the cell-specific binding moiety polypeptides comprises a polypeptide derived from a protein selected from the group consisting of selected from the group consisting of CD2, CD28, CTLA-4, CD40, and ligands thereof; fibrinogen; factor X; ICAM-1; β -glycan; Fc portion of immunoglobulin G; and a bacterial enterotoxin, or a subunit thereof.

64. (Amended) The method of claim 51, wherein the vaccine antigen is coated with one of the one or more recombinant cell-specific binding moiety polypeptides.

APPENDIX B

CLAIMS PENDING IN USSN 09/247,886 WITH ENTRY OF THIS AMENDMENT

2. (Amended Three Times) A method for obtaining a recombinant cell-specific binding moiety for an ability to increase uptake or specificity of a genetic vaccine for a target cell, the method comprising:

(1) recombining at least first and second forms of at least one nucleic acid, wherein each of the first and second forms of the nucleic acid comprises a polynucleotide that encodes a nucleic acid binding domain and at least first and second forms of at least one additional nucleic acid, wherein each of the first and second forms of the additional nucleic acid comprises a polynucleotide that encodes a cell-specific ligand that specifically binds to a protein on the surface of a cell of interest, wherein the first and second forms of each nucleic acid differ from each other in two or more nucleotides, to produce a library of recombinant binding moiety-encoding nucleic acids;

(2) producing a library of vectors from the library of recombinant binding moiety-encoding nucleic acids, wherein each vector comprises: a) a binding site specific for the nucleic acid binding domain and b) a member of the library of recombinant binding moiety-encoding nucleic acids;

(3) introducing one or more members of the library of vectors into one or more host cells, wherein the encoded recombinant binding moiety is expressed and recovering the expressed recombinant binding moiety;

(4) binding the expressed recombinant binding moiety to a vector comprising the binding site to form a vector-binding moiety complex;

(5) contacting the vector-binding moiety complex with a target cell of interest;
and

(6) determining if one or more target cells contain a vector from the vector-binding moiety complex, and recovering the recombinant cell-specific binding moiety nucleic acid from any such target cells.

3. (Amended Twice) The method of claim 2, wherein the method further comprises:

(7) recombining at least one recombinant binding moiety-encoding nucleic acid of (6) with a further form of the polynucleotide that encodes a nucleic acid binding domain and/or a further form of the polynucleotide that encodes a cell-specific ligand, which are the same or different from the first and second forms, to produce a further library of recombinant binding moiety-encoding nucleic acids;

(8) producing a further library of vectors from the further library of recombinant binding moiety-encoding nucleic acids, wherein each vector in the further library of vectors comprises: a) a binding site specific for the nucleic acid binding domain and b) a member of the further library of recombinant binding moiety-encoding nucleic acids;

(9) introducing one or more members of the further library of vectors into one or more host cells, wherein the encoded recombinant binding moiety is expressed and recovering the expressed recombinant binding moiety;

(10) binding the expressed recombinant binding moiety of (9) to a vector comprising the binding site to form a vector-binding moiety complex;

(11) contacting the vector-binding moiety complex of (10) with a target cell of interest and determining if one or more target cells contain a vector from the vector-binding moiety complex of (10);

(12) recovering the recombinant binding moiety-encoding nucleic acid from any such target cells of (11); and

(13) repeating (7) through (12) to screen for a cell-specific binding moiety useful for increasing uptake or specificity of a genetic vaccine vector for a target cell.

4. (Amended Once) The method of claim 2, wherein the method comprises screening for one or more cell-specific binding moieties that increase uptake of a genetic vaccine vector by the target cells.

5. (Amended Once) The method of claim 2, wherein the nucleic acid binding domain is a DNA binding domain derived from a protein selected from the group consisting of a transcriptional regulator, a polypeptide involved in DNA replication or recombination, a repressor, a histone, a protamine, an E. coli CAP protein, myc, a protein having a leucine zipper, a protein

having a DNA binding basic domain, a protein having a POU domain, a protein having a zinc finger, and a protein having a Cys3His (SEQ ID NO:6) box.

6. (As Filed) The method of claim 2, wherein the nucleic acid binding domain is an RNA binding domain derived from a protein selected from the group consisting of HIV *tat* and HIV *rev*.

7. (Amended Once) The method of claim 2, wherein the target cell of interest is selected from the group consisting of muscle cells, monocytes, dendritic cells, B cells, T cells, Langerhans cells, keratinocytes, M-cells, liver cells and epithelial cells.

8. (Amended Once) The method of claim 7, wherein the target cell of interest is a professional antigen presenting cell.

9. (As Filed) The method of claim 8, wherein the antigen presenting cell is a dendritic cell, a monocyte/macrophage, a B cell, or a Langerhans cell.

10. (Amended Once) The method of claim 8, wherein the cell-specific ligand comprises a polypeptide derived from a protein selected from the group consisting of CD2, CD28, CTLA-4, CD40 ligand, fibrinogen, ICAM-1, Fc portion of immunoglobulin G, and a bacterial enterotoxin, or a subunit thereof.

11. (As Filed) The method of claim 2, wherein the target cell of interest is a human cell.

12. (Amended Once) The method of claim 2, wherein target cells that contain the vector are identified by selecting for expression of a selectable marker contained in the vector.

13. (Amended Once) The method of claim 2, wherein each recombinant binding moiety-encoding nucleic acid comprises a genetic vaccine vector.

17. (Amended Twice) A composition for eliciting an immune response that comprises:

a) a recombinant binding moiety that comprises a nucleic acid binding domain and a cell-specific ligand, and

b) a polynucleotide sequence that is capable of expressing an antigen and that comprises a binding site, wherein the nucleic acid binding domain is capable of specifically binding to the binding site.

18. (Amended Four Times) A method for obtaining a recombinant cell-specific binding moiety for an ability to increase uptake, efficacy, or specificity of a vaccine or antigen for a target cell, the method comprising:

(1) recombining at least first and second forms of at least one nucleic acid, wherein each of the first and second forms of the nucleic acid comprises a polynucleotide which encodes a binding moiety polypeptide of an enterotoxin, wherein the first and second forms differ from each other in two or more nucleotides, to produce a library of recombinant nucleic acids;

(2) producing a library of vectors from the library of recombinant nucleic acids, wherein each vector comprises a member of the library of recombinant nucleic acids;

(3) introducing one or more members of the library of vectors into one or more host cells, wherein the one or more members of the library of recombinant nucleic acids are expressed to form one or more recombinant cell-specific binding moiety polypeptides and recovering the one or more recombinant cell-specific binding moiety polypeptides;

(4) contacting the one or more recombinant cell-specific binding moiety polypeptides with a cell surface receptor of a target cell; and

(5) determining which of the one or more recombinant cell-specific binding moiety polypeptides exhibits an enhanced ability to bind to the target cell compared to the ability of a binding moiety polypeptide encoded of (1) to bind to the target cell.

19. (Amended Once) The method of claim 18, wherein the cell surface receptor is present on the surface of a target cell during said contacting.

20. (As Filed) The method of claim 18, wherein the cell surface receptor is G_{M1} .

21. (As Filed) The method of claim 18, wherein the host cell is a *V. cholerae* cell which is incapable of expressing CT-A.

22. (Amended Twice) A method for producing a composition for eliciting an immune response, the method comprising coating a polynucleotide that is capable of expressing an

antigen with a recombinant cell-specific binding moiety polypeptide produced by the method of claim 18.

23. (Amended Twice) The method of claim 18, wherein each of the one or more recombinant cell-specific binding moiety polypeptides is expressed as a fusion protein on the surface of a replicable genetic package.

51. (Amended Twice) A method for obtaining a recombinant cell-specific binding moiety polypeptide for an ability to increase uptake, efficacy, or specificity of a vaccine antigen for a target cell, the method comprising:

(1) recombining at least first and second forms of at least one nucleic acid that comprises a polynucleotide which encodes a cell-specific binding moiety polypeptide, wherein the first and second forms differ from each other in two or more nucleotides, to produce a library of recombinant nucleic acids;

(2) introducing one or more members of a library of vectors, each of which comprises a member of the library of recombinant nucleic acids, into one or more host cells, wherein one or more members of the library of recombinant nucleic acids are expressed to form one or more recombinant cell-specific binding moiety polypeptides;

(3) contacting the one or more recombinant cell-specific binding moiety polypeptides with a cell surface receptor of a target cell;

(4) determining which of the one or more recombinant cell-specific binding moiety polypeptides exhibits an enhanced ability to bind to the target cell compared to the ability of the cell-specific binding moiety polypeptide of (1) to bind the target cell; and

(5) fusing or linking the recombinant cell-specific binding moiety polypeptide to the vaccine antigen or coating the vaccine antigen with the recombinant cell-specific binding moiety polypeptide.

52. (Amended) The method of claim 51, wherein each of the one or more recombinant cell-specific binding moiety polypeptides is expressed as a fusion protein on the surface of a replicable genetic package.

53. (Amended Twice) The method of claim 51, wherein each of the one or more recombinant cell-specific binding moiety polypeptides is fused or linked to the vaccine antigen.

54. (Amended Once) The method of claim 51, wherein the target cell is selected from the group consisting of muscle cells, monocytes, dendritic cells, B cells, T cells, Langerhans cells, keratinocytes, M-cells, liver cells and epithelial cells.

55. (Amended Once) The method of claim 51, wherein the cell surface receptor is present on the surface of a target cell during said contacting.

56. (Amended Twice) The method of claim 51, wherein each of the cell-specific binding moiety polypeptides comprises a polypeptide derived from a protein selected from the group consisting of selected from the group consisting of CD2, CD28, CTLA-4, CD40, and ligands thereof; fibrinogen; factor X; ICAM-1; β -glycan; Fc portion of immunoglobulin G; and a bacterial enterotoxin, or a subunit thereof.

57. A method for producing a composition for eliciting an immune response, said method comprising coating an antigen with a recombinant cell-specific binding moiety polypeptide produced by the method of claim 51.

58. A composition for eliciting an immune response comprising an antigen and a recombinant cell-specific binding moiety polypeptide, wherein the composition is produced by the method of claim 51, wherein:

- (i) the antigen comprises a polypeptide antigen;
- (ii) the cell-specific binding moiety polypeptide exhibits enhanced ability to bind to the target cell; and
- (iii) the polypeptide antigen and the recombinant cell-specific binding moiety polypeptide are derived from different polypeptides.

59. The method of claim 2, wherein the binding site of each vector is derived from a binding site present in at least one form of at least one nucleic acid of (1).

60. The method of claim 2, wherein the binding site is joined to the member of the library of recombinant binding moiety-encoding nucleic acids after said recombining.

61. The method of claim 2, wherein the vector-binding moiety complex forms inside the host cell and, prior to the contacting of (5), the host cell is lysed under conditions that do not disrupt the vector-binding moiety complex.

62. The method of claim 3, wherein the vector-binding moiety complex of (10) forms inside the host cell and, prior to the contacting of (11), the host cell is lysed under conditions that do not disrupt the vector-binding moiety complex.

63. The method of claim 2, wherein the cell-specific ligand comprises a polypeptide derived from a protein selected from the group consisting of CD2, CD28, CTLA-4, CD40, and ligands therefor; fibrinogen; factor X; ICAM-1; β -glycan; Fc portion of immunoglobulin G; and a bacterial enterotoxin, or a subunit thereof.

64. (Amended) The method of claim 51, wherein the vaccine antigen is coated with one of the one or more recombinant cell-specific binding moiety polypeptides.